UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II
290 BROADWAY
NEW YORK, NEW YORK 10007-1866

DATE: August 2, 2017

SUBJECT: Lower Passaic River Study Area, Baseline Human Health Risk Assessment, Consideration of Peer Review Handbook, 4th Edition

FROM: Jennifer LaPoma, Remedial Project Manager
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TO: File

The U.S. Environmental Protection Agency (EPA) Region 2 has evaluated the Baseline Human Health Risk Assessment (BHHRA) report (AECOM, 2017) for the Lower Passaic River Study Area (LPRSA) in consideration of the EPA's Peer Review Handbook, 4th Edition (USEPA, 2015). The LPRSA BHHRA has been performed in accordance with EPA's guidance on risk assessment and builds on a long history of assessments conducted by EPA and potentially responsible parties across the country under the Superfund program. Both the EPA guidance and the other risk assessments that served as precedents for the BHHRA were subject to external peer reviews and public comment.

The first through fourth editions of EPA's Peer Review Handbook discuss that a peer review may not be necessary if an application of an adequately peer-reviewed work product does not depart significantly from its scientific or technical approach or when the scientific or technical methodologies or information being used are commonly accepted in the field of expertise and have the appropriate documentation to support the commonly held view.

In the second edition of the Peer Review Handbook, and in later editions, the document discusses peer-input during the development of the product. During development of the LPRSA BHHRA work product, there was extensive interaction between EPA, the State and PRP consulting risk assessors. Under these circumstances including the on-going interaction and evaluation of comments received from all parties including a response to comments, a peer-review would not be necessary.

EPA has determined that the LPRSA BHHRA is not a work product that would be classified with any of the following designations: Influential Scientific Information (ISI), Highly Influential Scientific Assessment (HISA), or other scientific or technical work product designation. Consistent with the criteria set forth in Section 3 of the 4th Edition of the Peer Review Handbook and as outlined in the enclosed Peer Review Decision Summary Document, peer review of the work product is therefore not considered necessary. The LPRSA BHHRA does not establish significant precedent, model, or methodology that would require a peer review.

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References

AECOM. 2017. Baseline Human Health Risk Assessment for the Lower Passaic River Study Area, Final. Prepared for: Cooperating Parties Group, Newark, NJ. July.

USEPA. 2015. Peer Review Handbook, 4th Edition. Science and Technology Policy Council. EPA/100/B-15/001. October.

Enclosure 1

EPA Peer Review Decision Summary Documentation
(from Exhibit 3 on p. 15 of handbook)

1. **Work Product Title**: Baseline Human Health Risk Assessment for the Lower Passaic River Study Area
2. **Work Product Description**: Baseline human health risk assessment (BHHRA) prepared as part of the Lower Passaic River Study Area (LPRSA) remedial investigation/feasibility study (RI/FS) conducted under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly referred to as Superfund.

   The BHHRA was performed in accordance with EPA's guidance on risk assessment that includes guidance, policies, and guidelines from Superfund and other parts of the Agency. The report builds on a long history of assessments conducted by EPA and potentially responsible parties across the country under the Superfund program and meets the goals of the Superfund program for consistency in assessments. EPA guidance including Risk Assessment Guidance for Superfund (RAGS), guidelines (e.g., Dioxin Toxicity Equivalence Factors for Human Health, Guidelines for Carcinogen Risk Assessment, Supplemental Guidance for Early Childhood Susceptibility from Early Life Exposure to Carcinogens, Framework for Human Health Risk Assessment to Inform decisions), and policy (e.g., Role of the Baseline Risk Assessment OSWER Directive 9355.0-30) served as a basis for the BHHRA. The guidelines referenced above were developed by the Agency's Risk Assessment Forum and were subject to public comment and external peer review. Additionally, EPA used the Integrated Risk Information System (IRIS) chemical files for polychlorinated biphenyls (PCBs) and dioxin and other chemicals in the BHHRA that were made available for public comment and externally peer reviewed. Thus, the BHHRA does not establish significant precedent, model, or methodology that would require a peer review.

3. **Assistant Administrator (AA)-ship or Region and Originating Office/Division**: EPA Region 2/ Emergency and Remedial Response Division
4. **Decision/Rule/Regulation/Action/Activity That the Work Product Supports**: The forthcoming Record of Decision (ROD) for the LPRSA. Specifically, the BHHRA supports a decision about whether action is warranted at the LPRSA due to human health risks and the associated remediation levels that will be documented in an anticipated ROD.
5. **Categorization of Work Product**
   a. ___Influential Scientific Information (ISI)
   b. ___ Highly Influential Scientific Assessment (HISA)
   c. ___Other Scientific or Technical Work Product

6. **Rationale for Work Product Categorization and if Peer Review is needed**: Consistent with criteria identified in Section 3.3.2 of the handbook, peer review is not needed. The BHHRA was performed in accordance with EPA's guidance on risk including Superfund specific guidance such as Risk Assessment Guidance for Superfund Parts A through E. The assessment builds on a long history of assessments conducted by EPA and by potentially responsible parties across the country under the Superfund program. Thus, the BHHRA does not establish significant precedent, model or methodology that would require a peer review.
7. **Peer Review Mechanism(s) to Be Used, If Applicable (check all that apply)**: (If the work product is designated as ISI or a HISA, conduct peer review [unless exempted or deferred]. For other scientific or technical work products, peer review should be conducted if the Decision Maker [DM] determines that it is appropriate. Evaluate and allot sufficient resources, including funds, time and personnel.)
    a. _X_ Peer Review Not Necessary
    b. ___ Internal
    c. ___ External: Submit to Peer-Reviewed Journal
    d. ___ External: Letter Reviews
    e. ___ External: Contractor-Managed Panel
    f. ___ External: Federal Advisory Committee (FAC) (e.g., Science Advisory Board [SAB])
    g. ___ External: Other Panels (e.g., National Academy of Sciences [NAS])
8. **Opportunities for Public Participation (check all that apply)**:
    a. ___ Comment on Charge
    b. ___ Nominate Potential Peer Reviewers
    c. ___ Comment on Potential Peer Reviewers
    d. ___ Comment on Draft Work Product
    e. ___ Comment on Peer Review Mechanism
    f. ___ Oral Presentation to Reviewers

Documentation/Approval of Decision for Peer Review Not Necessary

Peer Review Coordinator (Concurrence) _____
Linda Mauel, EPA Region 2 Peer Review Coordinator
Date _____

Decision Maker (Approval) _____
John Prince, Acting Director, Emergency and Remedial Response Division
Date _____

Note: A peer review has not been deemed necessary. Therefore, a peer review leader has not been identified for this project.

EPA Peer Review Decision Summary Documentation: Explanation
(from Exhibit 3, page 16)

Designate the Work Product Category – DM and Peer Review Coordinator (PRC)		
Is Work Product Scientific or Technical (includes economic and social work products)?	3.1.1	No, The BHHRA was performed in accordance with EPA's guidance on risk assessment. The report builds on a long history of assessments conducted by EPA and potentially responsible parties across the country under the Superfund program and meets the goals of the Superfund program for consistency in assessments. EPA guidance including RAGS, guidelines (e.g., Dioxin Toxicity Equivalence Factors for Human Health, Guidelines for Carcinogen Risk Assessment, Supplemental Guidance for Early Childhood Susceptibility from Early Life Exposure to Carcinogens, Framework for Human Health Risk Assessment to Inform decisions), and policy (e.g., Role of the Baseline Risk Assessment OSWER Directive 9355.0-30) served as a basis for the BHHRA. The guidelines referenced above were developed by the Agency's Risk Assessment Forum and were subject to public comment and external peer review. Additionally, EPA used the IRIS chemical files for PCBs and dioxin and other chemicals in the BHHRA that were made available for public comment and externally peer reviewed. Thus, the BHHRA does not establish significant precedent,

		model, or methodology that would require a peer review.
If scientific or technical, which designation does the work product best fit:		
ISI: Will have or does have a clear and substantial impact on important public policies or private sector decisions. Decision makers should consider the following factors when determining whether a product is likely to be influential: a. Establishes a significant precedent, model or methodology.	3.2.1	a. This document does not meet the classification of an ISI.
b. Is likely to have an annual effect on the economy of $100 million or more.		b. No
c. Is likely to adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or state, tribal or local governments or communities		c. No
d. Addresses significant controversial issues		d. No
e. Focuses on significant emerging issues		e. No
f. Has significant cross-Agency/interagency implications		f. No
g. Involves a significant investment of Agency resources		g. No
h. Considers an innovative approach for a previously defined problem/process/methodology		h. No
i. Satisfies a statutory or other legal mandate for peer review		i. No
HISA: A scientific assessment (i.e., an evaluation of a body of scientific/technical knowledge that typically synthesizes multiple inputs, data, models and assumptions and/or applies best professional judgment to	3.2.3	a. No. The BHHRA would not have a potential impact of more than $500 million in any year.

bridge uncertainties in available information) that meets the following: a. In addition to meeting the criteria for ISI, could have a potential impact of more than $500 million in any year; or		
b. Is novel, controversial or precedent-setting or has significant interagency interest.		b. No.
Other	3.2.5	